CP Medical
Portland, OR USA

JUL 18 2007

K071550

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Device Name:	Pre-Waxed Needles with Gold Fiduciary Markers
Device Model Number:	FN17-xx, FN18-xx
Classification Name:	Implantable Radiographic Marker (NEU)
Device Classification:	Class II, 21 CFR 878.4300
Predicate Devices:	Best Radiopaque Marker, K043117
Manufacturer:	CP Medical 803 NE 25th Ave. Portland, OR 97232 USA
Establishment Registration Number:	3032563
Official Contact:	Betsy Cortelloni Regulatory Affairs Manager Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-271-0233 Fax: 770-831-4369

Intended Use: The needles are used for interstitial placement of gold seed markers. Once implanted, the gold markers serve as localization devices for the purpose of radiation therapy.

Device Description: The CP Medical Pre-waxed Needles with Gold Fiduciary Markers are designed for use in conjunction with conventional radiation therapy methods. The product consists of one (1) solid gold seed marker, loaded into a standard 17 or 18 gauge brachytherapy needle that has been preplugged with bone wax (CP Medical, K024372). The loaded needles are packaged individually or in groups of three. The packaged needles are sterilized via ethylene oxide.

Substantial Equivalence Comparison: The CP markers are compared to the gold "Radiopaque Marker" offered by Best Medical International, Inc. The two devices use equivalent materials and packaging.

Design Verification: The testing and verification activities performed for this product include sterilization validation and package validation. Product integrity was previously performed on the pre-waxed needles.

Conclusion: The results of verification testing confirmed that design inputs were achieved and that the CP Markers are substantial equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2007

CP Medical, Inc.
c/o Ms. Betsy Cortelloni
RA/QA Manager
Theragenics Corporation
5203 Bristol Industrial Way
BUFORD GA 30518

Re: K071550
Trade/Device Name: Pre-waxed Needles with Gold Fiduciary Markers
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: June 4, 2007
Received: June 6, 2007

Dear Ms. Cortelloni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(K) number (if known): K071550

Device Name: Pre-waxed Needles with Gold Fiduciary Markers

Indications for Use:

The needles are used for interstitial placement of gold seed markers. Once implanted, the gold markers serve as localization devices for the purpose of radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFRR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071550